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Moya Kinnealey

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DEC 04 2000

Applicant: Michael R. Hayden et al.

Art Unit: 1616

DEC 08 2000

Serial No.: 09/654,323

Examiner:

TECH CENTER 1600/2800

Filed: September 1, 2000

Title: Compositions and Methods for Modulating HDL Cholesterol and Triglyceride Levels

Assistant Commissioner For Patents
Washington, DC 20231**INFORMATION DISCLOSURE STATEMENT**

Applicant submits the references listed on the attached form PTO 1449.

Submission of this statement is not a representation that a search has been made nor is information included in this statement an admission that the information is material to patentability.

Under 35 USC 120, this application relies on the earlier filing date of application serial number 09/526,193, filed on March 15, 2000. Certain references were submitted to the Office in the prior application and, therefore, are not provided in this application. A copy of the previously submitted form PTO-1449 from the parent application is enclosed.

If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: November 29, 2000 Mary Rose Bergfors Reg. No. 36,268
for Paul T. Clark
Reg. No. 30,162

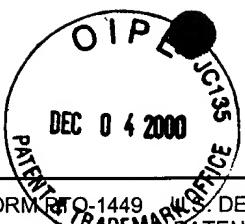
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\\Ntserver\\documents\\50110\\50110.004002 IDS.wpd

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Sheet 1 of 2

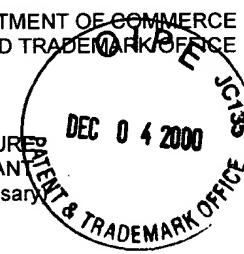
<p>SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)</p> <p>(37 CFR §1.98(b))</p>				Attorney Docket No.	50110/002005		
				Serial No.	09/526,193		
				Applicant	Michael R. Hayden et al.		
				Filing Date	March 15, 2000		
				Group			
				IDS Filed	November 6, 2000		
U.S. PATENTS							
Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)	
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION							
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)	
	WO 98/37764	03.09.98	PCT				
	WO 98/51351	19.11.98	PCT				
	WO 00/18912	06.04.00	PCT				
	WO 99/31133	24.06.99	PCT				
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)							
	Allikmets et al., "Organization of the ABCR Gene: Analysis of Promoter and Splice Junction Sequences," <i>Gene</i> 215:111-122 (1998).						
	Allikmets et al., "Characterization of the Human ABC Superfamily: Isolation and Mapping of 21 New Genes Using the Expressed Sequence Tags Database," <i>Hum. Mol. Genet.</i> 5:1649-1655 (1996).						
	Bodzioch et al., "The Gene Encoding ATP-binding Cassette Transporter 1 Is Mutated in Tangier Disease," <i>Nat. Genet.</i> 22:347-351 (1999).						
	Borst P., "Multidrug Resistant Proteins," <i>Semin. Cancer Biol.</i> 3:131-134 (1997).						
	Brooks-Wilson et al., "Mutations in ABC1 in Tangier Disease and Familial High-density Lipoprotein Deficiency," <i>Nat. Genet.</i> 22:336-345 (1999).						
	Dean et al., "Evolution of ATP-binding Cassette Transporter Genes," <i>Curr. Opin. Gen. Dev.</i> 5:779-785 (1995).						
	Drobnick et al., "Activation of Phosphatidylinositol-Specific Phospholipase C in Response to HDL Sub 3 and LDL is Markedly Reduced in Cultured Fibroblasts From Tangier Patients," <i>Arterioscler. Thromb. Vasc. Biol.</i> 15:1369-1377 (1995).						
	Kuivenhoven et al., "Heterogeneity at the CETP Gene Locus: Influence on Plasma CETP Concentrations and HDL Cholesterol Levels," <i>Arterioscler. Thromb. Vasc. Biol.</i> 17:560-568 (1997).						
	Langmann et al., "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages," <i>Biochemical and Biophysical Research Communications</i> 257:29-33 (1999).						
	Lawn et al., "The Tangier Disease Gene Product ABC1 Controls the Cellular Apolipoprotein-mediated Lipid Removal Pathway," <i>J. Clin. Invest.</i> 104:R25-R31 (1999).						
	Luciani et al., "Cloning of Two Novel ABC Transporters Mapping on Human Chromosome 9," <i>Genomics</i> 21:150-159 (1994).						
	Marcil et al., "Cellular Cholesterol Transport and Efflux in Fibroblasts Are Abnormal in Subjects With Familial HDL Deficiency," <i>Arterioscler. Thromb. Vasc. Biol.</i> 19:159-169 (1999).						
EXAMINER			DATE CONSIDERED				
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Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)	
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)							
	Remaley <i>et al.</i> , "Human ATP-binding Cassette Transporter 1 (ABC1): Genomic Organization and Identification of the Genetic Defect in the Original Tangier Disease Kindred," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96:12685-12690 (1999).						
	Rogler <i>et al.</i> , "HDL-Mediated Efflux of Intracellular Cholesterol Is Impaired in Fibroblasts From Tangier Disease Patients," <i>Arterioscler. Thromb. Basc. Biol.</i> 15:683-690 (1995).						
	Rust <i>et al.</i> , "Assignment of Tangier Disease to Chromosome 9q31 by a Graphical Linkage Exclusion Strategy," <i>Nature Genetics</i> 20:96-98 (1998).						
	Rust <i>et al.</i> , "Tangier disease is caused by mutations in the gene encoding ATP-binding cassette transporter 1," <i>Nature Genetics</i> 22:352-355 (1999).						
	Savary <i>et al.</i> , "Isolation and Chromosomal Mapping of a Novel ATP-binding Cassette Transporter Conserved in Mouse and Human," <i>Genomics</i> 41:275-278 (1997).						
	Schmitz <i>et al.</i> , "ATP-binding Cassette Transporter A1 (ABCA1) in Macrophages: A Dual Function in Inflammation and Lipid Metabolism?," <i>Pathobiology</i> 67:236-240 (1999).						
	Wilson <i>et al.</i> , "2.2 Mb of Contiguous Nucleotide Sequence From Chromosome III of <i>C. Elegans</i> ," <i>Nature</i> 368:32-38 (1994).						
	GenBank Accession No. AF165281						
	GenBank Accession No. P41233						
	GenBank Accession No. NM_005502						
	GenBank Accession No. X75926						
	GenBank Accession No. A54774						
	GenBank Accession No. AAC69223						
	GenBank Accession No. CAA10005						
	GenBank Accession No. AJ012376						
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SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket No.	50110/004002
		 DEC 04 2000 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	09/654,323
				Applicant	Michael R. Hayden et al.
				Filing Date	September 1, 2000
				Group	IDS Filed
				November 29, 2000, 1600/2900	
(37 CFR §1.98(b))					

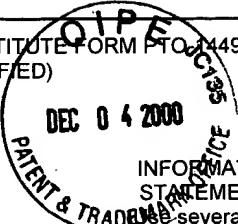
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	Allikmets et al., "Characterization of the Human ABC Superfamily: Isolation and Mapping of 21 New Genes Using the Expressed Sequence Tags Database," <i>Hum. Mol. Genet.</i> 5:1649-1655 (1996).					
DJS	Apfel et al., "A novel orphan receptor specific for a subset of thyroid hormone-responsive elements and its interaction with the retinoid/thyroid hormone receptor subfamily," <i>Molecular and Cellular Biology</i> 14:7025-7035 (1994).					
DJS	Bodzioch et al., "The Gene Encoding ATP-binding Cassette Transporter 1 Is Mutated in Tangier Disease," <i>Nat. Genet.</i> 22:347-351 (1999).					
	Borst P., "Multidrug Resistant Proteins," <i>Semin. Cancer Biol.</i> 3:131-134 (1997).					
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	Drobnick et al., "Activation of Phosphatidylinositol-Specific Phospholipase C in Response to HDL Sub 3 and LDL is Markedly Reduced in Cultured Fibroblasts From Tangier Patients," <i>Arterioscler. Thromb. Vasc. Biol.</i> 15:1369-1377 (1995).					
DJS	Janowski et al., "An oxysterol signalling pathway mediated by the nuclear receptor LXR α ," <i>Nature</i> 383:728-731 (1996).					
	Kuivenhoven et al., "Heterogeneity at the CETP Gene Locus: Influence on Plasma CETP Concentrations and HDL Cholesterol Levels," <i>Arterioscler. Thromb. Vasc. Biol.</i> 17:560-568 (1997).					
	Langmann et al., "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages," <i>Biochemical and Biophysical Research Communications</i> 257:29-33 (1999).					
	Lawn et al., "The Tangier Disease Gene Product ABC1 Controls the Cellular Apolipoprotein-mediated Lipid Removal Pathway," <i>J. Clin. Invest.</i> 104:R25-R31 (1999).					
DJS	Lehmann et al., "Activation of the nuclear receptor LXR by oxysterols defines a new hormone response pathway," <i>Journal of Biological Chemistry</i> 272:3137-3140 (1997).					
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(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(several sheets if necessary)

(37 CFR §1.98(b))

Attorney Docket No.	50110/004002
Serial No.	09/654,323
Applicant	Michael R. Hayden et al.
Filing Date	September 1, 2000
Group	
IDS Filed	November 8, 2000

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	Luciani et al., "Cloning of Two Novel ABC Transporters Mapping on Human Chromosome 9," <i>Genomics</i> 21:150-159 (1994).
	Marcil et al., "Cellular Cholesterol Transport and Efflux in Fibroblasts Are Abnormal in Subjects With Familial HDL Deficiency," <i>Arterioscler. Thromb. Vasc. Biol.</i> 19:159-169 (1999).
DJS	Peet et al., "Cholesterol and bile acid metabolism are impaired in mice lacking the nuclear oxysterol receptor LXRa," <i>Cell</i> 93:693-704 (1998).
	Remaley et al., "Human ATP-binding Cassette Transporter 1 (ABC1): Genomic Organization and Identification of the Genetic Defect in the Original Tangier Disease Kindred," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96:12685-12690 (1999).
	Rogler et al., "HDL-Mediated Efflux of Intracellular Cholesterol Is Impaired in Fibroblasts From Tangier Disease Patients," <i>Arterioscler. Thromb. Vasc. Biol.</i> 15:683-690 (1995).
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DJS	Rust et al., "Tangier disease is caused by mutations in the gene encoding ATP-binding cassette transporter 1," <i>Nature Genetics</i> 22:352-355 (1999).
	Savary et al., "Isolation and Chromosomal Mapping of a Novel ATP-binding Cassette Transporter Conserved in Mouse and Human," <i>Genomics</i> 41:275-278 (1997).
	Schmitz et al., "ATP-binding Cassette Transporter A1 (ABCA1) in Macrophages: A Dual Function in Inflammation and Lipid Metabolism?," <i>Pathobiology</i> 67:236-240 (1999).
DJS	Song et al., "Ubiquitous receptor: a receptor that modulates gene activation by retinoic acid and thyroid hormone receptors," <i>Proc. Natl. Acad. Sci. USA</i> 91:10809-10813 (1994).
DJS	Willey et al., "LXR, a nuclear receptor that defines a distinct retinoid response pathway," <i>Genes & Development</i> 9:1033-1045 (1995).
	Wilson et al., "2.2 Mb of Contiguous Nucleotide Sequence From Chromosome III of <i>C. Elegans</i> ," <i>Nature</i> 368:32-38 (1994).
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